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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,913	08/21/2003	Herbert Peter Jennissen	034258-1401	8136

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,913	JENNISSEN, HERBERT PETER	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 7/10/06 in response to an office action of 2/9/06 amended claims 32, 35 and 41-44, and added new claims 45 and 46.

Claims examined on the merits are 32-46, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 32-34, 41, 42 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 and claims dependent thereon are confusing and unclear by claim 32 in lines 7 and 8 requiring biomolecules (a) and (b), and in line 9 requiring an additional biomolecule without it being labeled as (c). In line 9 before "reduces" it appears --- (c) --- should be inserted to be clear that the biomolecule in line 9 is alternative to that required by (a) and (b).

Claim 42 is unclear by not having antecedent basis for "the metal component" (bridging lines 1 and 2). Claim 32 does not require a metal "component". This also applies to "the metallic alloy component" (line 3) and "the ceramic component" (line 4). In each instance, "component" should be deleted.

Claim 44 is unclear by not having antecedent basis for "the metal implant material" (line 2), "the metallic alloy implant material"

(bridging lines 3 and 4), and "the ceramic implant material" (line 4). Claim 44 depends on claims 43 and 35, and these claims do not require a metal implant material, metallic alloy implant material and a ceramic implant material.

Claim Rejections - 35 USC § 103

Claims 32-37 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sukenikk et al (WO 92/00047) in view of Vosika et al (WO 90/09798) taken with Senter et al (5,306,307) or Mueller et al (5,837,235) for reasons in the previous office action of 2/9/06, and for reasons herein.

The claims are drawn to attaching mediator molecules to an implant material by covalently bonding anchor groups having functional groups and then attaching mediator molecules to the functional groups. The mediator molecules can be BMP, an ubiquitin or an antibiotic, and the implant material can comprise a metal, a metallic alloy or a ceramic material. In claim 38, a spacer is bound to the anchor molecule, and the mediator molecule is bound to the spacer.

Sukenikk et al disclose attaching a monolayer having functional groups to an implant surface and then coating with an adhesion mediating molecule. The surface may be oxidized and contain oxide groups (Figs 1 and 5, and page 29, lines 13-26).

Vosika et al disclose coupling cytokines to a support having functional groups by attaching a linking arm to the functional groups and then attaching a cytokine to the linking arm (paragraph bridging pages 23 and 24, and page 24, lines 8-29).

Senter et al (paragraph bridging cols 3 and 4) and Mueller et al (col 3, lines 32-49) disclose a metal implant containing BMP to promote bone formation.

It would have been obvious to attach the mediator molecule of Sukenikk et al using a linking arm as suggested by Vosika et al since this would have been expected to provide an effective way of attaching the mediator molecule by covalent bonding. The linking arm is inherently an anchor molecule. It would have been further obvious to use the linking arm to attach BMP as suggested by Senter et al or Mueller et al when desiring to obtain the function of BMP to promote bone formation. The limitations of dependent claims would have been matters of obvious choice in view of the disclosures of the references.

Response to Arguments

The response urges that Sukenikk et al bind fibronectin to the implant surface using hydrogen bonding, van der Waals interactions or ion pairing that result in non-covalent bonding, which is unstable and unsuitable for a long term implant, whereas the present invention mediator molecule is covalently bonded to an anchor or spacer molecule.

This argument is unpersuasive since claim 32 (line 6), claim 35 (line 6) and claim 38 (line 9) require immobilizing the mediator molecule on the implant material, but do not requiring the immobilizing to be by covalent bonding of the mediator molecule to the functional group. Furthermore, Sukenikk et al does not state that

using hydrogen bonding, van der Waals interactions or ion pairing is critical, but that these are included as examples of how bonding can be performed. Also, Vosika et al covalently bind a cytokine to a support, and it would have been obvious that covalent bonding is an alternative bonding method to using hydrogen bonding, van der Waals interactions or ion pairing. Groups X disclosed by Sukenikk et al (Fig. 1) include groups such as COOH, CN and OH that are well known to be capable of forming covalent bonds. The result of a covalent bond being stable would have been obvious since covalent bonds are well known to be more stable than bonds formed by only adsorption resulting from hydrogen bonding, van der Waals interactions or ion pairing. Fibronectin used as an adhesion molecule by Sukenikk et al can function as a mediator molecule. As to claims requiring BMP as the molecule, Senter et al and Mueller et al disclose using BMP to promote bone formation. It would have been obvious to substitute BMP for the fibronectin when its function to promote bone formation is desired.

The response urges that Vosika et al use organic biodegradable supports. However, the supports disclosed by Vosika et al include metals (page 22, line 27). Certain metals are biocompatible and can be implanted, and Vosika et al disclose using either non-biodegradable or biodegradable supports (page 21, line 8).

It is granted that Senter et al and Mueller et al do not covalently bond BMP. However, these references are combined with the Vosika et al reference, which would have suggested covalent bonding. BMP is a protein and the cytokines of Vosika et al include proteins.

It would have been expected BMP can be covalently bonded in the same way as the cytokines. While Mueller et al use a sponge as the support, both Sukenikk et al and Vosika et al disclose a metal as the support, and the use of a metal would have been obvious.

Comments set forth above also apply to claims 35, 36 and 44. As noted above, the use of BMP in place of the fibronectin would have been obvious when the function of BMP rather than fibronectin is desired. As to claim 36, BMP-2 and BMP-7 and their function are well known, and the selection of these BMPs would have been obvious.

Claim Rejections - 35 USC § 103

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 32-37 and 41-45 above, and further in view of Matsumoto et al (4,371,612) for reasons in the previous office action and for reasons herein.

The claims require a spacer molecule to be bound to the anchor molecule and the mediator molecule to be bound to the spacer. The spacer can reduce nonspecific binding.

Matsumoto et al disclose direct bonding or using a spacer when binding a biological material to a polymer (col 5, lines 55-57).

When modifying Sukenikk et al as set forth above, it would have been obvious to use a spacer as suggested by Matsumoto et al to obtain space between the carrier and material immobilized. The spacer would have inherently reduced nonspecific binding as in claim 39.

Response to Arguments

The response urges that Matsumoto et al bond biological material such as enzymes to a water insoluble polymer, and do not suggest using a modified polymer as an implant material and the use of morphogens such as BMP to coat the implant surface. However, Matsumoto et al is not applied alone, but in combination with other references that would have suggested a polymer implant containing attached BMP. The covalent bonding reactions disclosed by Matsumoto et al are sufficiently similar to those disclosed by Vosika et al that it would have been expected a spacer can be used for covalently coupling a mediator molecule to the support of Sukenikk et al. An unexpected result has not been established in using a spacer as claimed as compared to the use of a spacer by Matsumoto et al.

Claim Rejections - 35 USC § 103

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 32-37 and 41-45 above, and further in view of Goldstein (4,002,602), and if necessary in further view of Goldstein et al (4,190,647) (both newly applied).

The claim requires ubiquitin as the mediator molecule.

Goldstein discloses a ubiquitous polypeptide that has the ability to induce in vitro differentiation of both T cell and B cell immunocytes (abstract and col 2, lines 55-60).

Goldstein et al disclose that the ubiquitous polypeptide has been renamed ubiquitin (col 2, line 33).

It would have been obvious to substitute for the fibronectin of Sukenikk et al, the ubiquitous polypeptide disclosed by Goldstein to obtain the function of the polypeptide to induce cell differentiation as taught by Goldstein. The ubiquitous polypeptide being named ubiquitin would have been apparent from Goldstein et al, if needed.

Double Patenting

Claims 32-37 and 41-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,635,269 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed method of immobilizing a mediator molecule on an implant encompasses the method of the patent claims of immobilizing a mediator molecule on an implant.

Double Patenting

Claims 38 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,635,269 B1 as set forth above, and in view of Matsumoto et al. Matsumoto et al would have suggested the use of a spacer in the claims of the patent for the reason set forth above when applying Matsumoto et al.

Response to Arguments

The response states that these issues will be addressed in due course pending resolution of all other issues in the case, e.g., by submission of a terminal disclaimer or other action as may be appropriate.

Conclusion

Claim 40 is free of the prior art.

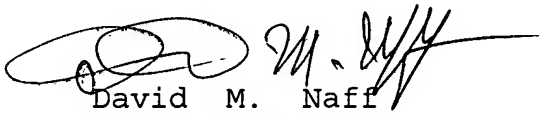
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
9/26/06